MEDICATION GUIDE
ZALEPLON (ZAH-le-plon) CAPSULES, USP C-IV

Read this Medication Guide before you start taking zaleplon capsules and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. You and your doctor should talk about zaleplon capsules when you start taking them and at regular checkups.

What is the most important information I should know about zaleplon capsules?

After taking zaleplon capsules, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with zaleplon capsules. Reported activities include:

- driving a car ("sleep-driving")
- making and eating food
- talking on the phone
- having sex
- sleep-walking

Important:

1. Take zaleplon capsules exactly as prescribed
- Do not take more zaleplon capsules than prescribed.
- Take zaleplon capsules right before you get in bed, not sooner.

2. Do not take zaleplon capsules if you:
- drink alcohol
- take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take zaleplon capsules with your other medicines
- cannot get a full night's sleep

3. Call your doctor right away if you find out that you have done any of the above activities after taking zaleplon capsules.

What are zaleplon capsules?
Zaleplon capsules are a sedative-hypnotic (sleep) medicine. Zaleplon capsules are used in adults for the short-term treatment of the symptom of trouble falling asleep from insomnia. Zaleplon capsules do not treat other symptoms of insomnia which include waking up too early in the morning and waking up often during the night.

Zaleplon capsules are not for children.

Zaleplon capsules are a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep zaleplon capsules in a safe place to prevent misuse and abuse. Selling or giving away zaleplon capsules may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take zaleplon capsules?
Do not take zaleplon capsules if you are allergic to anything in them. See the end of this Medication Guide for a complete list of ingredients in zaleplon capsules.

Zaleplon capsules may not be right for you. Before starting zaleplon capsules, tell your doctor about all of your health conditions, including if you:
- have a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- have kidney or liver disease
- have a lung disease or breathing problems
- are pregnant, planning to become pregnant, or breastfeeding

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Medicines can interact, sometimes causing side effects. **Do not take zaleplon capsules with other medicines that can make you sleepy.**

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take zaleplon capsules?
- **Take zaleplon capsules exactly as prescribed.** Do not take more zaleplon capsules than prescribed for you.
- **Take zaleplon capsules right before you get into bed.** Or you can take zaleplon capsules after you have been in bed and have trouble falling asleep.
- Do not take zaleplon capsules with or right after a meal.
- **Do not take zaleplon capsules unless you are able to get a full night's sleep before you must be active again.**
- **Call your healthcare provider if your insomnia worsens or is not better within 7 to 10 days.** This may mean that there is another condition causing your sleep problem.
- If you take too much zaleplon capsules or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of zaleplon capsules?
Serious side effects of zaleplon capsules include:

- **getting out of bed while not being fully awake and do an activity that you do not know you are doing.** (See "What is the most important information I should know about zaleplon capsules?")
- **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.
- **memory loss**
- **anxiety**
- **severe allergic reactions.** Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking zaleplon capsules.

Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using zaleplon capsules.
Common side effects of zaleplon capsules include:

- drowsiness
- lightheadedness
- dizziness
- "pins and needles" feeling on your skin
- difficulty with coordination
- You may still feel drowsy the next day after taking zaleplon capsules.
  Do not drive or do other dangerous activities after taking zaleplon capsules until you feel fully awake.
- You may have withdrawal symptoms when you stop taking zaleplon capsules. Withdrawal symptoms include unpleasant feelings, stomach and muscle cramps, vomiting, sweating, shakiness, and rarely seizures. You may also have more trouble sleeping the first few nights after zaleplon capsules are stopped. The problem usually goes away on its own after 1 or 2 nights.

These are not all the side effects of zaleplon capsules. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store zaleplon capsules?

- Store zaleplon capsules at room temperature between 68° and 77° F (20° to 25°C).
- Protect from light.
- **Keep zaleplon capsules and all medicines out of the reach of children.**

General Information about zaleplon capsules

- Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide.
- Do not use zaleplon capsules for a condition for which they were not prescribed.
- Do not give zaleplon capsules to other people, even if they have the same condition. They may harm them and it is against the law.

This Medication Guide summarizes the most important information about zaleplon capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about zaleplon capsules that was written for healthcare professionals.

What are the ingredients in zaleplon capsules?
Active Ingredient: zaleplon, USP
Inactive Ingredients: lactose monohydrate, pregelatinized starch, microcrystalline cellulose, silicon dioxide, magnesium stearate, gelatin, titanium dioxide, FD&C blue #1, FD&C red #40, and FD&C yellow #5. Ink constituents are: shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide and potassium hydroxide.

- **Zaleplon capsules 5 mg** – Dark green colored cap and Light blue colored body, "size 4" hard gelatin capsules imprinted with "ZLP" on body and "2122" on cap with black ink, filled with white to off white granular powder.
- **Zaleplon capsules 10 mg** - Dark green colored cap and Opaque blue body, "size 4" hard gelatin capsules imprinted with "ZLP" on body and "2130" on cap with black ink, filled with white to off white granular powder.

Medication Guides available at www.northstarrxllc.com/products or call 1-800-206-7821.

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